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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,311	06/25/2003	Binnur Ozturk	204.001	5252

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MEREDITH & KEYHANI, PLLC
330 MADISON AVE.
6TH FLOOR
NEW YORK, NY 10017

EXAMINER	
LAMM, MARINA	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/603,311	OZTURK ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-9 and 65-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-9 and 65-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/13/07 has been entered.

2. Claims pending are 1, 4-9 and 65-83. Claims 2 and 3 have been cancelled.

3. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejection of Claims 1, 4-9, 65, 67-80 and 82 under 35 U.S.C. 103(a) as being unpatentable over Wolicki (US 2004/0101582) in view of either Williams et al. (US 2003/0082214) or Murdock et al. (US 6,572,880) is maintained for the reasons of the record.

6. The rejection of Claims 66, 81 and 83 under 35 U.S.C. 103(a) as being unpatentable over Wolicki (US 2004/0101582) in view of either Williams et al. (US 2003/0082214) or Murdock et al. (US 6,572,880) and further in view of Kobayashi et al. (EP 581 587) is maintained for the reasons of the record.

Response to Arguments

7. Applicant's arguments filed 4/25/07 have been fully considered but they are not persuasive.

In response to the Applicant's argument that there is no suggestion to combine the references (see pp. 2-4 of the remarks), the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation

to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Wolicki teaches transdermal compositions useful for relieving pain, **inflammation** and irritation associated with skin diseases and disorders as discussed above. Wolicki does not teach the claimed anti-inflammatory component. However, Williams et al. teach using non-steroidal anti-inflammatory analgesics such as acetylsalicylic acid, ketoprofen, indometacin, etc. in transdermal compositions for treating pain. Similarly, Murdock et al. teach ketoprofen in combination with gabapentin and/or amitriptyiline in transdermal compositions for pain relief. Therefore, using conventional anti-inflammatory compounds such as ketoprofen, for their art-recognized purpose, in the compositions of Wolicki would be a logical choice for one skilled in the art. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Wolicki such that to use an anti-inflammatory agent such as ketoprofen. One having ordinary skill in the art would have been motivated to do this to obtain an additional pain relieving effect as suggested by either Williams et al. or Murdock et al. It has been long held that selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). The strongest rationale for combining references is a recognition, expressly or implicitly in

the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. See *In re Sernaker* 17 USPQ 1, 5-6 (Fed. Cir. 1983) and MPEP 2144. In this case, the advantageous and expected beneficial result would be pain-relieving effect as discussed above.

In response to the Applicant's argument that the Williams reference "teaches directly away from the present invention" (see p. 4 of the remarks), it is noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See *In re Susi*, 169 USPQ 423 (CCPA 1971). A known or obvious composition is not patentable simply because it has been described as somewhat inferior to some other product for the same use. See *In re Gurley,* 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See MPEP 2123.

In response to the Applicant's argument that the Wolicki reference teaches away from the present invention by stating that NSAIDs when taken **orally** cause gastric distress and other side effects (see p. 4 of the remarks; emphasis added), it is noted neither neither the reference nor the instant invention is directed to **oral** compositions. This statement in Wolicki is taken out of the context and cannot be reasonably interpreted as teaching away from using NSAIDs in **topical** or **transdermal** compositions.

In response to the Applicant's arguments that "there is not reasonable expectation of success" (see p. 5 of the remarks), it is noted that one of ordinary skill in

the art of pharmaceutical compositions would have a reasonable expectation of success when using an anti-inflammatory agent such as ketoprofen, in transdermal compositions of Wolicki because (1) Wolicki's transdermal compositions are used for relieving pain and inflammation and (2) ketoprofen is a known anti-inflammatory agent.

In response to the Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private

PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.
Patent Examiner
9/14/07

SHENGJUN WANG
PRIMARY EXAMINER